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K033137

Section D. 510(k) SUMMARY

POTENS+

This summary of safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and the final rule under 21 CFR 807.92 published December 14, 1994.

(A)(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

Submitter's Name: WADA, Inc

Submitter's Address: 1556 San Leandro Lane, Montecito, CA 93108

Submitter's Telephone: 805-969-2758

Submitter's Contact: Gail Rodrick-Highberg (510-792-1527)

Date 510(k) Summary Prepared: September 19, 2003

(a)(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known.

Trade or Proprietary Name: POTENS+

Common or usual Name: Multipurpose System for In Vitro Coagulation Studies:

Classification Name: Multipurpose System for In Vitro Coagulation Studies.

(a)(3) An identification of the legally marketed device to which the submitter claims substantial equivalence.

Device equivalent to:

Organon Tecknika Coag-A-Mate MTX (K962857) for Fibrinogen
Organon Tecknika MDA-180 (K924453) for PT & INR

(a)(4) A description of the device

Device description: Semi-automated system for in vitro coagulation studies, clot based and photo-optical.

(a)(5) A statement of the intended use of the device

Device Intended Use: POTENS+ is a multipurpose system for use in performing clot based, photo-optical in-vitro coagulation studies including Prothrombin Time (PT) derived Fibrinogen (FBG), and the International Normalization Ratio (INR).

(a)(6) The summary of the technological characteristics of the new device in comparison to those of the predicate device.

POTENS+, MTX and MDA-180 are multipurpose systems capable of performing in-vitro coagulation studies; all three perform clot-based assays.

Table 1 below outlines the similarities/differences between the POTENS+, MTX and MDA-180.

Table 1

Similarities and Difference Between POTENS+, MTX and the MDA-180

	POTENS+ (Test Device)	**CAM-MTX (Predicate Device)**	**MDA-180 (Predicate Device)**
Analytes	PT, FBG and INR	FBG	PT, FBG and INR
Methodology	Fibrin Clot based assay; optical measurement of direct light transmission during clot formation.	Clauss method: Fibrin Clot based assay; optical measurement of relative light transmission to the time of clot formation.	Clauss method: Fibrin Clot based assay; optical measurement of relative light transmission to the time of clot formation.
Instrument system	Potentiophotometer , Reagent Dispenser, Pipettor, Heating block, computer and printer	Analyzer (measuring rotor and photometer), computer and printer	Multi-Channel Discrete Analyzer
Principles of operation	Detects change in light transmittance at 660nm	Detects change in light transmittance at 405 nm	Detects change in light transmittance in the spectral range 405 to 710 nm. FBG @ 425 nm PT @ 580 nm
Method of Detection	Optical (LED with silicon photovoltaic cell)	Optical using a photometer and detectors	Optical (tungsten lamp) using photodiode detectors
Signal Processing	Linear handling of light transmission using digital electronics	Logarithmic conversion of light transmission using analog electronics	Logarithmic handling of light transmission using analog electronics
Reagents/ Accessories	Calibration Standards (2) Controls (3) Reagent Water Test Cuvettes Cuvette rack Normal saline Thromboplastin (Dade® Thromboplastin C Plus)	Reference Plasma (for calibration) Verify Controls: Veronal Buffer Sample cups Cuvette Rotor Fibriquik (Thrombin)	VeriCal Calibrator Set Verify Controls Reagent Water Probe Cleaner Buffer Test Cuvettes Clauss Reagents (Thrombin, Imidiazole buffer)
Operating Temp	37 ± 0.3°C	37°C	37 ± 1°C
Test Sample	Citrated plasma	Citrated plasma	Citrated plasma
Test Sample Dilution	Not required	Required	Required

(b)(1) A brief discussion of the nonclinical tests submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalency.

Testing was performed to determine correlation and bias, precision and interfering substances. Interfering substances, and specimen collection and preparation are well documented for these type of assays are in accordance with NCCLS standards and recommendations of the International Society of Thrombosis and Hemostasis.

(b)(2) A brief discussion of the clinical tests submitted, reference, or relied in the premarket notification submission for a determination of substantial equivalency.

A comparison study was conducted using patent specimens over the normal, diagnostic and therapeutic range. Correlation coefficients (r-values) ranged from for 0.973 to 0.980 for Fibrinogen, 0.95 to 0.974 for PT and 0.919 to 0.963 for INR results. Total precision for Fibrinogen was well within NCCLS recommendations using human based and bovine based control plasmas. Total precision for PT and INR using human based control plasmas were also well within NCCLS recommendations.

(b)(3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better that the legally marketed device identified in (a)(3),

The performance characteristics of the POTENS+ are comparable to those of the predicate devices. The data presented in the premarket notification demonstrate that the POTENS+ performs substantially equivalent to the predicate devices. Comparison studies were performed to demonstrate that POTENS+ is equivalent to the MTX for determining Fibrinogen concentration and to the MDA-180 for determining PT and INR results.

Equivalence was demonstrated using commercially available methods/product along with patient specimens covering the normal, therapeutic and diagnostic range. Correlation coefficients (r-values) ranged from for 0.973 to 0.980 for Fibrinogen, 0.95 to 0.974 for PT and 0.919 to 0.963 for INR results.

Precision studies were performed following the guidelines in NCCL EP5A "Evaluation of Precision Performance of Clinical Chemistry Devices". Total precision coefficient of variations (CVs) were less than 6% for fibrinogen using normal and abnormal control plasma, less than 5% for PT using normal and abnormal human control plasma and less than 8% for INR using normal and abnormal human control plasma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Wada Inc.
c/o Ms. Gail Rodrick-Highberg
Regulatory Consultant
Highberg Associates
35949 Nicolet Court
Fremont, California 94536

Re: k033137
Trade/Device Name: POTENS+
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose System for in vitro Coagulation Studies
Regulatory Class: II
Product Code: JPA
Dated: September 29, 2003
Received: September 30, 2003

Dear Ms. Rodrick-Highberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section C. STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known) K033137

Device Name: POTENS+

Indications for Use:

POTENS+ is an *in vitro* medical device to determine the coagulation profile of citrated human plasma specimens to be used by a medical professional in a laboratory setting. This profile includes Prothrombin Time (PT) derived Fibrinogen (FBG), and the International Normalization Ratio (INR).

Prothrombin Time is used to determine the status of the extrinsic clotting pathway for Clotting Factors I, II, V, VII and X, and to assist in monitoring oral anticoagulants.

Fibrinogen is used to diagnose disseminated intravascular coagulation (DIC), as a representation of acute disease – part of the "acute phase response," and it is an independent risk variable in heart attack and stroke prediction.

INR is used to monitor the patients receiving anticoagulation therapy.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033137

Rx ✓